EXHIBIT B

Allergan, Inc. v. Sandoz Inc., 818 F. Supp. 2d 974 (E.D. Tex. 2011) *aff'd in part, rev'd in part*, 726 F.3d 1286 (Fed. Cir. 2013)

United States Court of Appeals for the Federal Circuit

ALLERGAN, INC.,
Plaintiff-Appellee,

v.

SANDOZ INC., ALCON LABORATORIES, INC., ALCON RESEARCH, LTD., ALCON, INC., AND FALCON PHARMACEUTICALS, LTD.,
Defendants-Appellants,

AND

APOTEX INC. AND APOTEX CORP.,
Defendants-Appellants,

AND

WATSON LABORATORIES, INC.,
Defendant-Appellant.

2011-1619, -1620, -1635, -1639

Appeals from the United States District Court for the Eastern District of Texas in consolidated No. 09-CV-0097, Judge T. John Ward.

Decided: May 1, 2013

JUANITA R. BROOKS, Fish & Richardson P.C., of San Diego, California, argued for plaintiff-appellee. With her

on the brief were JONATHAN E. SINGER and DEANNA J. REICHEL, of Minneapolis, Minnesota; W. CHAD SHEAR, of Wilmington, Delaware.

DEANNE E. MAYNARD, Morrison & Foerster, LLP, of Washington, DC, argued for all defendants-appellants. With her on the brief was BRIAN R. MATSUI; BRIAN M. KRAMER, of San Diego, California. Of counsel on the brief were KERRY B. MCTIGUE, BARRY P. GOLOB, and W. BLAKE COBLENTZ, Duane Morris LLP, of Washington, DC. Also on the brief were ROBERT B. BREISBLATT, STEPHEN P. BENSON, CHRISTINE E. BESTOR and DENNIS C. LEE, Katten, Muchin & Rosenman LLP, of Chicago, Illinois, for defendants-appellants Apotex Inc., et al, and GARY E. HOOD, Polsinelli Shughart PC, of Chicago, Illinois, for defendant-appellant Watson Laboratories, Inc. Of counsel was RICHARD T. RUZICH, Katten, Muchin & Rosenman LLP, of Chicago, Illinois, for defendants-appellants Sandoz Inc., et al.

Before DYK, PROST, and O'MALLEY *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* PROST. Opinion concurring-in-part and dissenting-in-part filed by *Circuit Judge* DYK.

This patent infringement case involves a combination ophthalmic drug treatment. The issues on appeal are invalidity and claim construction. Sandoz Inc., Alcon Laboratories, Inc., Alcon Research Ltd., Alcon, Inc., and Falcon Pharmaceuticals, Ltd. (collectively, "Sandoz") challenge the district court's finding that the claims of U.S. Patent Nos. 7,642,258 ("'258 patent"); 7,320,976 ("'976 patent"); 7,323,463 ("'463 patent"); and 7,030,149 ("'149 patent") are not invalid under 35 U.S.C. § 103. Allergan challenges the court's construction of certain claims. We find that the district court erred in finding the claims of the '463 patent not invalid as obvious. The

defendants, however, failed to prove by clear and convincing evidence that claim 4 of the '149 patent would have been obvious. Additionally, we find no error in the district court's claim construction. Accordingly, we affirm-in-part and reverse-in-part.

I. PROCEDURAL HISTORY

This action arises under the Hatch-Waxman Act, which enables the approval and marketing of generic drugs. Each of the Appellants in this case submitted to the U.S. Food and Drug Administration ("FDA") an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of Allergan's Combigan®, a combination eye-drop product used for treating glaucoma comprising 0.2% brimonidine and 0.5% timolol. Allergan sued under 35 U.S.C. § 271(e)(2)(A) claiming that the Appellants infringed each and every claim of Allergan's four Orange Book-listed patents for Combigan® including the '258, '976, '463, and '149 patents, each of which stems from an application filed on April 19, 2002. According to the Orange Book, the '258, '976, and '149 patents expire on April 19, 2022 and the '463 patent expires on January 19, 2023.

Prior to trial, but after claim construction, the district court granted summary judgment of non-infringement as to claims 1-3 of the '149 patent. The parties stipulated to infringement of the other asserted claims. As such, the only issue tried to the district court was the issue of invalidity. After a bench trial, the court entered judgment finding each of the asserted claims not invalid.

On appeal, Sandoz challenges the district court's finding that the asserted claims are not invalid as obvious under 35 U.S.C. § 103. Allergan attempted to cross-appeal the district court's construction of claims 1-3 of the '149 patent and the subsequent entry of summary judgment of non-infringement. We found that, with respect to Allergan, there was no adverse judgment on the validity

of claims 1-3 of the '149 patent and, therefore, a cross-appeal would be improper. *Allergan, Inc. v. Sandoz Inc.*, 2012 U.S. App. LEXIS 6926, *6 (Fed. Cir. Apr. 4, 2012). We did, however, explain that Allergan was free to raise their claim construction arguments in its response brief as part of the present appeal. *Id.*

II. BACKGROUND

Combigan®, which is used to treat glaucoma, is a combination of the well-known alpha$_2$-agonist Alphagan® (0.2% brimonidine) and the well-known beta-blocker Timoptic® (0.5% timolol), both of which are also used to treat glaucoma. Notably, Combigan® contains the preservative benzalkonium chloride ("BAK"), which is widely-used in ophthalmic formulations including Alphagan® and Timoptic®.

A. The Asserted Claims

Allergan holds four patents related to Combigan®: the '463 patent, the '149 patent, the '258 patent, and the '976 patent. The asserted claims are directed to a composition of 0.2% brimonidine and 0.5% timolol, expressed in different ways, some claims are directed to a fixed combination of brimonidine and timolol, others are directed to a method of treating glaucoma or ocular hypertension by administering the composition twice daily, and others are directed to an article of manufacture comprising packaging material indicating that twice daily administration of the composition is useful for treating glaucoma or ocular hypertension. Claim 1 of the '463 patent is exemplary and provides:

> 1. A composition comprising about 0.2% timolol by weight and about 0.5% brimonidine by weight as the sole active agents, in a single composition.

The other claims of the '463 patent include additional limitations directed to the amount of BAK in the composition and to packaging material that indicates that the

composition is useful for treating glaucoma or ocular hypertension by twice a day topical administration of the composition to a person's eye. In their briefs, the parties generally treat the claims as a group and, with the exception of claim 4 of the '149 patent, do not argue them individually. As such, with the exception of claim 4, we treat the claims collectively.

Claim 4 of the '149 patent is directed to reducing the daily number of doses of brimonidine without loss of efficacy by administering brimonidine in a fixed combination with timolol. Claim 4 reads as follows:

> 4. A method of *reducing the number of daily topical ophthalmic doses of brimondine* administered topically to an eye of a person in need thereof for the treatment of glaucoma or ocular hypertension *from 3 to 2 times a day without loss of efficacy*, wherein the concentration of brimonidine is 0.2% by weight, said method comprising administering said 0.2% brimonidine by weight and 0.5% timolol by weight in a single composition.

B. The Prior Art

Sandoz's obviousness argument is based primarily upon U.S. Patent No. 5,502,052 titled "Use of a Combination of Apraclonidine and Timolol to Control Intraocular Pressure" ("DeSantis"), which teaches fixed combinations of alpha$_2$-agonists and beta-blockers for the treatment of glaucoma. DeSantis explains that a significant number of glaucoma patients require more than one drug to achieve therapeutic reduction of intraocular pressure. col. 1 ll. 42-46. DeSantis also teaches that then-existing treatment regimens requiring administration of two or more medications in separate, spaced dosages, several times a day often resulted in poor patient compliance, particularly in elderly patients. col. 2 ll. 1-9. DeSantis teaches the amount of alpha$_2$-agonist included in the fixed combination is from 0.02 to 2.0% by weight. col. 4 ll. 58-61.

DeSantis expressly teaches the use of the beta-blocker timolol in a fixed combination with alpha$_2$-agonists. col. 5 l. 34. Moreover, timolol is the only beta-blocker claimed in DeSantis. col. 6 ll.4 2-48. DeSantis teaches that the preferred amount of beta-blocker in the fixed combination is from 0.01 to 3.0% by weight. col. 5 ll. 37-40. DeSantis also discloses the use of BAK as a preservative. col. 5 l. 41–col. 6 l. 1. DeSantis specifically discloses BAK when it discusses "formulatory ingredients" such as "benzalkonium chloride" that "will typically be employed in an amount of from, about 0.001% to 1.0% by weight (wt. %)." *Id.*

DeSantis does not expressly state that brimonidine is one of the alpha$_2$-agonists that can be used in the combination. DeSantis does, however, teach that the alpha$_2$-agonists that may be used in the invention are described in a publication by Timmermans et al. titled "Structure-Activity Relationships in Clonidine-Like Imidazolidines and Related Compounds," which DeSantis incorporates by reference. col. 4 ll. 43-50. Timmermans discloses both brimonidine and its tartrate salt. J.A. 1093–94; J.A. 1104–05.

Sandoz adduced other evidence relevant to obviousness. For instance, at the time of the invention, the topical administration of 0.2% brimonidine with 0.5% timolol in combination—spaced five minutes apart—was taught in an article published in the Archives of Ophthalmology, titled "Aqueous Humor Flow in Normal Human Eyes Treated With Brimonidine and Timolol" ("Larsson"). Additionally, it was common at the time of the invention to dose the serial application of brimonidine and timolol twice per day rather than the three times per day as was common to stand alone brimonidine therapy. J.A. 633–36; *see also* J.A. 7586. It was also known that both the commercially available forms of brimonidine and timolol contained BAK. J.A. 60.

Moreover, at the time of the invention, there were only three known pharmaceutically acceptable alpha$_2$-agonists for treating glaucoma or ocular hypertension, clonidine, apraclonidine, and brimonidine. J.A. 587–89, 780, 537. At that time, only brimonidine was available in the United States for chronic use. J.A. 536–37. There were at least four other fixed combination products for the treatment of ocular hypertension and glaucoma on the market at the time of invention. J.A. 631. Additionally, the prior art taught advantages associated with certain fixed combinations including a 1998 article in Journal of the American Academy of Ophthalmology by Clineschmidt that concluded that a fixed combination of dorzolamide and timolol dosed twice a day was more effective than dorzolamide alone dosed three times a day; and a 1987 article in American Journal of Ophthalmology by Airaksinen that concluded that the fixed combination of timolol and pilocarpine dosed twice a day had a similar intraocular pressure reduction as pilocarpine alone dosed four times a day.

III. OBVIOUSNESS

The determination of obviousness under 35 U.S.C. § 103 is a legal conclusion based on underlying facts. *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966). After a bench trial, we "review the district court's factual findings for clear error and its conclusions of law *de novo.*" *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1344–45 (Fed. Cir. 2000).

The underlying factual considerations in an obviousness analysis include the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, and any relevant secondary considerations. *See Graham*, 383 U.S. at 17–18. Relevant secondary considerations include commercial success, long-felt but unsolved needs, failure of others, and unexpected results. *KSR Int'l Co. v. Tele-*

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flex Inc., 550 U.S. 398, 406 (2007); *In re Soni*, 54 F.3d 746, 750 (Fed.Cir. 1995). Patents are presumed valid; accordingly, Sandoz was required to prove that the asserted claims were obvious by clear and convincing evidence. *See Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011).

A. The '463 Patent

Sandoz makes a strong case that the claims of the '463 patent would have been obvious. Both timolol and brimonidine were commercially available drugs used for opthamalic conditions at the time of the invention. Moreover, they were available in their claimed concentrations, contained the preservative BAK, and the commercially available form of brimonidine—Alphagan®—contained BAK in the claimed concentration. At the time of the invention, it was known that the serial administration of brimonidine and timolol reduced intraocular pressure greater than either timolol or brimonidine alone. Moreover, DeSantis expressly provided a motivation to formulate fixed combinations of alpha$_2$-agonists and beta blockers, including timolol, in order to increase patient compliance.

In finding that Sandoz failed to prove the asserted claims obvious, the district court made a series of findings that are relevant to the obviousness analysis. First, the court found that there would be no motivation to create the combination product because the FDA did not view patient compliance as a factor for approval. Second, the court found that the formulation arts are unpredictable. Third, the court also found that there were some teachings in the prior art that taught away from the claimed invention. Finally, the court found that there were secondary considerations that support the finding of nonobviousness including long-felt need and unexpected results. We discuss each of these findings in turn.

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1. Motivation to Combine

As noted above, DeSantis provides an express motivation to combine alpha$_2$-agonists and beta blockers in order to increase patient compliance. The district court, however, found that "while patient compliance may have created a need for fixed combination products, it did not motivate a person of skill in the art to develop fixed combinations with a reasonable expectation of success, because the FDA did not consider improving patient compliance as a factor in its approval decision." *Allergan, Inc. v. Sandoz Inc.*, 818 F. Supp. 2d 974, 1016 (E.D. Tex. 2011). We agree with the district court that FDA approval may be relevant to the obviousness analysis, however, we find clear error in the court's conclusion that one of ordinary skill would not be motivated to develop fixed combinations with a reasonable expectation of success.

We have previously noted that FDA approval may be relevant to the obviousness inquiry. *See Knoll Pharm. Co., Inc. v. Teva Pharms. USA, Inc.*, 367 F.3d 1381, 1385 (Fed. Cir. 2004) (considering the failure of others to obtain FDA approval as relevant objective indicia of nonobviousness). The potential for FDA approval also may properly be considered, as it was here, in determining whether one of ordinary skill would be motivated to develop a drug product and whether there was skepticism regarding the efficacy of such a product. Nevertheless, we find the district court erred in concluding that one of ordinary skill would not be motivated to develop a fixed combination product to increase patient compliance because the FDA did not consider that particular motivation when evaluating drug applications. There is no requirement in patent law that the person of ordinary skill be motivated to develop the claimed invention based on a rationale that forms the basis for FDA approval. Motivation to combine may be found in many different places and forms; it cannot be limited to those reasons the FDA sees fit to consider in approving drug applications.

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When viewed under the proper standard, the evidence of record establishes a motivation to combine brimonidine and timolol into a fixed combination product. Not only does DeSantis teach the fixed combination of timolol with an alpha$_2$-agonist, numerous other references teach the fixed combination of other ophthalmic drugs. *Allergan, Inc.*, 818 F. Supp. 2d at 1016-17. In fact, there were at least four other fixed combination products for the treatment of ocular hypertension and glaucoma on the market at the time of invention. J.A. 631. Moreover, it was common at the time of the invention to provide brimonidine and timolol to a patient in serial fashion and DeSantis taught that by combining drugs in a fixed-combination formulation, patient compliance could be increased. Accordingly, we find clear error in the district court's finding that there was no motivation to develop a fixed combination brimonide/timolol product.

2. Reasonable Expectation of Success

The district court found that unpredictability in the chemical arts also weighed in favor of nonobviousness. In reaching this conclusion, the district court relied both on general statements regarding the unpredictability associated with developing drug formulations and specific challenges associated with the development of Combigan®. While we agree that formulation science carries with it a degree of unpredictability, "obviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007). Here, there was a reasonable expectation of success based upon the teachings of DeSantis. DeSantis showed that alpha$_2$-agonists and beta blockers are complementary and should be used together. DeSantis further provided that BAK could be successfully used in the formulation. In view of DeSantis, one of ordinary skill would have a reasonable expectation

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of success in formulating a fixed combination product containing brimonidine, timolol, and BAK.

We find no error in the district court's factual finding that Allergan's formulators faced difficulties in developing Combigan®. However, these difficulties are not particularly probative with respect to obviousness for a number of reasons. For example, the claims are not drawn to the Combigan® formulation with any specificity given that Combigan® contains many elements in addition to those embodied in the claims. There is no requirement that one of ordinary skill have a reasonable expectation of success in developing Combigan®. Rather, the person of ordinary skill need only have a reasonable expectation of success of developing the claimed invention. More importantly, much of the formulators' struggles were associated with their attempts to utilize a proprietary preservative, rather than BAK. There is little evidence that once the formulators switched their focus to BAK they struggled to develop a formulation containing the claimed composition of brimonidine, timolol, and BAK. Accordingly, we find that the district court erred in finding that there was no reasonable expectation of success in view of the general unpredictability of the formulation arts and particularized, yet irrelevant, difficulties associated with the development of Combigan®.

3. Teaching Away

The district court also found that certain aspects of the prior art taught away from the claimed invention including the potential side effects, the different dosing regimens in commercially available forms of brimonidine and timolol, and the disparate half-lives of brimonidine and timolol. Notably, the district court did not consider what, if any, impact these aspects of the prior art would have on the clear motivation to combine expressed in DeSantis. Moreover, the district court did not find that the prior art as a whole taught away from the invention

and we will not do so now on appeal. While we accept the district court's factual findings on these matters, we cannot conclude that they render the invention nonobvious.

4. Secondary Factors

Finally, the court found that there were secondary considerations that support the finding of nonobviousness including long-felt need and unexpected results. We accept the district court's factual findings regarding the existence of these secondary factors; however, we conclude that these factors do not weigh heavily in the obviousness analysis.

With respect to long-felt need, the district court's findings are entirely conclusory. The district court, without explanation, found that there was a need for combination products and that Combigan®, at some level, met that need. Such perfunctory language provides us with little help in performing our de novo review of obviousness.

The district court also found that unexpected results weigh in favor of nonobviousness. Specifically, the court found that there was increased efficacy of the drug and a reduction in side-effects. The court found that previous attempts to treat patients twice per day with brimonidine resulted in a loss of efficacy eight to nine hours post administration. This loss of efficacy is referred to as the "afternoon trough." The court found that a twice per day dosage regimen of Combigan® unexpectedly did not suffer from the afternoon trough issue. We agree with the court's finding that this result was unexpected. However, we do not find that these unexpected results are sufficient to outweigh the other evidence of obviousness as to these formulation claims. While the unexpected benefits of twice a day dosing of the combination formula are relevant to Sandoz's attack on the validity of the method claims, we do not find it similarly meaningful to our

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analysis of the formulation claims. There is extensive evidence in the prior art showing the concomitant administration of brimonidine and timolol multiple times per day, that the combination had benefits over the administration of either alone, and that there was a motivation to combine the two to achieve better patient compliance. *KSR*, 550 U.S. at 426. Whether or not that combination also solved problems associated with the afternoon trough, we find the motivation to make the combination was real. Accordingly, we conclude that the claims of the '463 patent are invalid as obvious.

B. The '149 Patent

The district court also found that claim 4 of the '149 patent was not invalid as obvious. Claim 4 is similar to the claims of the '463 patent with the exception that it contains the additional limitation that the daily number of doses of brimonidine be reduced from 3 to 2 times a day *without loss of efficacy*. Sandoz has the burden to show by clear and convincing evidence that claim 4 would have been obvious. *See Microsoft Corp*, 131 S. Ct. at 2242. On this front, Sandoz has a problem.

The record firmly establishes that when brimonidine is dosed twice per day as opposed to three times per day, there is a loss of efficacy in the afternoon—the so called, afternoon trough. Sandoz has failed to point to evidence in the prior art that would allow us to conclude that the addition of timolol to brimonidine dosed twice per day would eliminate the afternoon trough issue. At the outset, we note that Sandoz does not argue that this efficacy limitation is inherent to fixed combination products containing timolol and brimonidine, nor that a dose reduction without loss of efficacy would inherently flow from the obvious fixed-combination of timolol and

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brimonidine.[1] Moreover, while it is true that the prior art shows concomitant administration of brimonidine and timolol was dosed twice per day, this art does not show that there was no loss of efficacy associated with that treatment, let alone an elimination of the afternoon trough.

Sandoz attempts to bolster its argument by showing that, at the time of the invention, timolol had been combined with other ophthalmic drugs, though not alpha$_2$-

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[1] The dissent would find claim 4 obvious on the grounds that it merely claims the result of treatment with an obvious composition. In support of its position, the dissent cites a series of cases in which a patentee claimed either a previously unknown result or an undisclosed inherent property of an otherwise anticipated claim. In the context of anticipation, "[n]ewly discovered results of known processes directed to the same purpose are not patentable because such results are inherent." *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001). We agree with the dissent that the inherency doctrine may apply to an otherwise obvious claim as well. There is, however, a problem with applying that doctrine in this case.

The evidence of record does not establish that the dose reduction "from 3 to 2 times a day without loss of efficacy" limitation is an inherent property or a necessary result of the administration of 0.2% brimonidine and 0.5% timolol in a single composition. Of course, it may be true that the mere administration of 0.2% brimonidine and 0.5% timolol twice daily in any fixed combination formulation inherently produces the claimed result. Alternatively, it may also be true that only certain fixed-combination formulations produce this result. On the present record, we cannot draw a conclusion in favor of either proposition.

agonists, to effectively treat glaucoma with a reduced number of doses. However, we see no reason why the success of unrelated drugs would make it obvious to one of ordinary skill that a fixed combination of brimonidine and timolol could be dosed twice per day without loss of efficacy. Similarly, Sandoz attempts to rely on DeSantis's teaching that fixed-combination drug products will have a greater reduction in intraocular pressure than either drug alone. Even if we accept that this generalized teaching of DeSantis is true for all fixed-combination products, we cannot equate a greater reduction in intraocular pressure with "no loss of efficacy" as required by claim 4, particularly where, as the trial court found, DeSantis did not provide clinical data on any of the possible combinations it disclosed. Accordingly, we find that Sandoz failed to prove by clear and convincing evidence that claim 4 of the '149 patent is invalid as obvious.[2]

IV. CLAIM CONSTRUCTION

Allergan argues that the district court erred in construing claims 1-3 of the '149 patent. Claim 1, from which claims 2 and 3 depend, recites:

> 1. A method of treating glaucoma or ocular hypertension by topical administration of about 0.2% brimonidine by weight to an eye of a person in need thereof, said improvement comprising topically administering to said eye, in a single composition, about 0.2% brimonidine by weight and about 0.5% timolol by weight twice a day; as the sole active agents; wherein said method is as

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[2] The '258, '976, and '149 patents each expire on April 19, 2022. Because we conclude that claim 4 of the '149 patent is not invalid, the Appellants will be unable to enter the market until that date. Accordingly, we find it unnecessary to address the claims of the '258 and '976 patents.

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> effective as administration of 0.5% timolol twice a day and 0.2% brimonidine three times a day to said eye, wherein *the two compounds are administered in separate compositions*.

The district court construed the term "administered in separate compositions" to require that serial administration of brimonidine and timolol be compared to the fixed-combination product. Allergan argues that the claims should be construed as comparing either drug individually to the combination product. Sandoz argues that the limitation of applying the separate compositions to "said eye" would make no sense unless the claim required serial application of the two drugs. We find no error in the district court's construction. Rather, the plain language of the claim contemplates the administration of both compositions to the same eye be compared to the fixed combination product.

In conclusion, we find that the district court erred in finding the claims of the '463 patent not invalid as obvious. However, we find that the defendants failed to prove by clear and convincing evidence that claim 4 of the '149 patent would have been obvious. Finally, we find no error in the district court's claim construction.

AFFIRM-IN-PART AND REVERSE-IN-PART

United States Court of Appeals for the Federal Circuit

ALLERGAN, INC.,
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v.

SANDOZ INC., ALCON LABORATORIES, INC., ALCON RESEARCH, LTD., ALCON, INC., AND FALCON PHARMACEUTICALS, LTD.,
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WATSON LABORATORIES, INC.,
Defendant-Appellant.

2011-1619, -1620, -1635, -1639

Appeals from the United States District Court for the Eastern District of Texas in consolidated No. 09-CV-0097, Judge T. John Ward.

DYK, *Circuit Judge*, concurring in part and dissenting in part.

I join in the majority's holding that the claims of U.S. Patent No. 7,323,463 ("the '463 patent") are invalid as

obvious, and that the district court correctly construed the relevant claims of the patents. I would hold, however, that claim 4 of U.S. Patent No. 7,030,149 ("the '149 patent") is also invalid as obvious.

Claim 4 of the '149 patent recites:

> *A method of reducing the number of daily topical ophthalmic doses of brimondine* [sic] administered topically to an eye of a person in need thereof for the treatment of glaucoma or ocular hypertension *from 3 to 2 times a day without loss of efficacy*, wherein the concentration of brimonidine is 0.2% by weight, *said method comprising administering said 0.2% brimonidine by weight and 0.5% timolol by weight in a single composition*.

'149 patent col. 10 ll. 10-17 (emphases added).

The majority concludes, correctly, that the composition claimed in the '463 patent would have been obvious, even though it has the unexpected property that it can be dosed twice a day without a loss of efficacy (specifically, without the appearance of a so-called "afternoon trough"). Yet the majority affirms the validity of a claim drawn to the method of dosing that same composition twice a day, because the prior art did not disclose that this dosing regimen "would eliminate the afternoon trough issue." Maj. Op. 13. I think that the different results as between the claims of the '463 patent and claim 4 of the '149 patent cannot be reconciled.

While a new and nonobvious *method of using* an existing (or obvious) composition may itself be patentable, *see Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1378 (Fed. Cir. 2005), a newly-discovered *result or property* of an existing (or obvious) *method of use* is not patentable. *See Abbott Labs. v. Baxter Pharm. Prods.*, 471 F.3d 1363, 1368-69 (Fed. Cir. 2006); *Brassica Prot. Prods. LLC v.*

Sunrise Farms (In re Cruciferous Sprout Litig.), 301 F.3d 1343, 1350-51 & n.4 (Fed. Cir. 2002); *Bristol-Myers Squibb Co. v. Ben Venue Labs.*, 246 F.3d 1368, 1376 (Fed. Cir. 2001).

In this case, the method of claim 4 consists of a single step: applying a fixed combination of 0.2% brimonidine and 0.5% timolol twice a day. *See* '149 patent col. 10 ll. 10-17. This method was surely obvious to try. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). The majority recognizes that "it was common at the time of the invention to dose the serial application of brimonidine and timolol twice per day," and that "the prior art shows concomitant administration of brimonidine and timolol . . . dosed twice per day." Maj. Op. 6, 14. Moreover, the record shows that reducing the number of daily doses of anti-glaucoma drugs was seen as valuable for improving patient compliance and for reducing exposure to toxic ingredients. The method of applying a fixed combination of 0.2% brimonidine and 0.5% timolol twice a day would therefore have been obvious over the prior art.

The majority's outcome appears to rest, therefore, on the notion that claim 4 was not obvious because it claims the result of twice-a-day dosing—avoiding "a loss of efficacy in the afternoon." *See* Maj. Op. 13. Avoiding a "loss of efficacy" is not a separate step, but rather a result of the claimed method. *See Bristol-Myers Squibb*, 246 F.3d at 1374-78; *see also Abbott Labs.*, 471 F.3d at 1369. We should recognize in this case, as we did in *Bristol-Myers Squibb*, that "[n]ewly discovered results of known processes directed to the same purpose are not patentable." *Bristol-Myers Squibb*, 246 F.3d at 1376.[1]

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[1] The majority appears not to dispute that claiming the result of an otherwise unpatentable process cannot render the process patentable, but suggests that this rule should not apply here because there may exist specific

For these reasons, I respectfully dissent from the majority's holding that claim 4 of the '149 patent is not invalid as obvious.

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formulations of a fixed combination of 0.2% brimonidine and 0.5% timolol that do not inherently achieve this result. *See* Maj. Op. 14 n.1. Claim 4, however, is not limited to any particular formulation. *See* '149 patent col. 10 ll. 10-17. The majority's argument therefore only suggests that the claim would have been even more clearly obvious, since it would cover the use of compositions that do not even achieve the allegedly unexpected result. "Claims [that] are broad enough to read on obvious subject matter are unpatentable even though they also read on nonobvious subject matter." *In re Lintner*, 458 F.2d 1013, 1015 (CCPA 1972); *see also ArcelorMittal Fr. v. AK Steel Corp.*, 700 F.3d 1314, 1325 (Fed. Cir. 2012) (citing *Lintner*); *Muniauction, Inc. v. Thomson Corp.*, 532 F.3d 1318, 1328 n.4 (Fed. Cir. 2008) (same).

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

INFORMATION SHEET

FILING A PETITION FOR A WRIT OF CERTIORARI

There is no automatic right of appeal to the Supreme Court of the United States from judgments of the Federal Circuit. You must file a petition for a writ of certiorari which the Supreme Court will grant only when there are compelling reasons. (See Rule 10 of the Rules of the Supreme Court of the United States, hereinafter called Rules.)

Time. The petition must be filed in the Supreme Court of the United States within 90 days of the entry of judgment in this Court or within 90 days of the denial of a timely petition for rehearing. The judgment is entered on the day the Federal Circuit issues a final decision in your case. [The time does not run from the issuance of the mandate, which has no effect on the right to petition.] (See Rule 13 of the Rules.)

Fees. Either the $300 docketing fee or a motion for leave to proceed in forma pauperis with an affidavit in support thereof must accompany the petition. (See Rules 38 and 39.)

Authorized Filer. The petition must be filed by a member of the bar of the Supreme Court of the United States or by the petitioner representing himself or herself.

Format of a Petition. The Rules are very specific about the order of the required information and should be consulted before you start drafting your petition. (See Rule 14.) Rules 33 and 34 should be consulted regarding type size and font, paper size, paper weight, margins, page limits, cover, etc.

Number of Copies. Forty copies of a petition must be filed unless the petitioner is proceeding in forma pauperis, in which case an original and ten copies of the petition for writ of certiorari and of the motion for leave to proceed in forma pauperis. (See Rule 12.)

Where to File. You must file your documents at the Supreme Court.

Clerk
Supreme Court of the United States
1 First Street, NE
Washington, DC 20543
(202) 479-3000

No documents are filed at the Federal Circuit and the Federal Circuit provides no information to the Supreme Court unless the Supreme Court asks for the information.

Access to the Rules. The current rules can be found in Title 28 of the United States Code Annotated and other legal publications available in many public libraries.

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Questions and Answers

Petitions for Panel Rehearing (Fed. Cir. R. 40)
and
Petitions for Hearing or Rehearing En Banc (Fed. Cir. R. 35)

Q. When is a petition for panel rehearing appropriate?

A. Petitions for panel rehearing are rarely considered meritorious. Consequently, it is easiest to first answer when a petition for panel rehearing is not appropriate. A petition for panel rehearing should not be used to reargue issues already briefed and orally argued. If a party failed to persuade the court on an issue in the first instance, they do not get a second chance. This is especially so when the court has entered a judgment of affirmance without opinion under Fed. Cir. R. 36, as a disposition of this nature is used only when the appellant/petitioner has utterly failed to raise any issues in the appeal that require an opinion to be written in support of the court's judgment of affirmance.

Thus, as a usual prerequisite, the court must have filed an opinion in support of its judgment for a petition for panel rehearing to be appropriate. Counsel seeking panel rehearing must be able to identify in the court's opinion a material error of fact or law, the correction of which would require a different judgment on appeal.

Q. When is a petition for rehearing en banc appropriate?

A En banc decisions are extraordinary occurrences. To properly answer the question, one must first understand the responsibility of a three-judge merits panel of the court. The panel is charged with deciding individual appeals according to the law of the circuit as established in the court's precedential opinions. While each merits panel is empowered to enter precedential opinions, the ultimate duty of the court en banc is to set forth the law of the Federal Circuit, which merits panels are obliged to follow.

Thus, as a usual prerequisite, a merits panel of the court must have entered a precedential opinion in support of its judgment for a petition for rehearing en banc to be appropriate. In addition, the party seeking rehearing en banc must show that either the merits panel has failed to follow decisions of the Supreme Court of the United States or Federal Circuit precedential opinions, or that the merits panel has followed circuit precedent, which the party seeks to have overruled by the court en banc.

Q. How frequently are petitions for panel *rehearing granted by merits panels or petitions for rehearing en banc granted by the court?*

A. The data regarding petitions for panel rehearing since 1982 shows that merits panels granted some relief in only three percent of the petitions filed. The relief granted usually involved only minor corrections of factual misstatements, rarely resulting in a change of outcome in the decision.

En banc petitions have been granted less frequently. Historically, the court has initiated en banc review in a few of the appeals decided en banc since 1982.

Q. Is it necessary to have filed either of these petitions before filing a petition for certiorari in the U.S. Supreme Court?

A. No. All that is needed is a final judgment of the Court of Appeals.

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

NOTICE OF ENTRY OF JUDGMENT ACCOMPANIED BY OPINION

OPINION FILED AND JUDGMENT ENTERED: 05/01/2013

The attached opinion announcing the judgment of the court in your case was filed and judgment was entered on the date indicated above. The mandate will be issued in due course.

Information is also provided about petitions for rehearing and suggestions for rehearing en banc. The questions and answers are those frequently asked and answered by the Clerk's Office.

No costs were taxed in this appeal.

Regarding exhibits and visual aids: Your attention is directed Fed. R. App. P. 34(g) which states that the clerk may destroy or dispose of the exhibits if counsel does not reclaim them within a reasonable time after the clerk gives notice to remove them. (The clerk deems a reasonable time to be 15 days from the date the final mandate is issued.)

FOR THE COURT

/s/ Jan Horbaly

_____

Jan Horbaly
Clerk

Stephen P. Benson
Christine Bestor
Robert Breisblatt
Juanita Rose Brooks
William Blake Coblentz
Barry P. Golob
Gary Edward Hood
Brian M. Kramer
Dennis C. Lee
Brian Robert Matsui
Deanne Maynard
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Deanna Jean Reichel
Richard T. Ruzich
W. Chad Shear
Jonathan Elliot Singer
11-1619 - Allergan, Inc. v. Sandoz Inc.
United States District Court for the Eastern District of Texas, Marshall Case No. 09-CV-0097, 09-CV-0348, 10-CV-200, 10-CV-0344